

dilator has an axial tension force applied to it to contract the tubular member diametrically, and to extend it axially.

United Kingdom Patent Application No. 2,135,585A to Wallsten discloses a prosthesis for transluminal implantation comprising a flexible tubular body which has a diameter that is variable by axial movement of the ends of the body and which is composed of several individual rigid, but flexible thread elements, each of which extends in a helix configuration. The flexible tubular body is brought to expand radially outwardly in several ways such as: the expanded state of the body may be dependent on the inherent rigidity of thread elements, but it may also be controlled by elastic strings, bands, or membranes...." (P. 4, ll. 29-35; P. 5, ll. 1-5). As set forth on page 4 of the Wallsten specification, it is preferred that the Wallsten device has the property of "entering into radially expanded and unloaded position by itself".

#### REMARKS

At the outset, it should be noted that it is Applicant's belief that the liner, or sleeve, disclosed in the Hammerslag Patent is inoperable for the embodiment disclosed wherein the sleeve, or liner, is conveyed by a balloon catheter. The basis of this belief is that, insofar as the liner, or sleeve, is made from a material having substantially the same elasticity as the human artery, expansion of such a liner by a balloon catheter will not operate in the manner described in the Hammerslag Patent. Although the sleeve or liner may well be expanded by the balloon catheter, upon deflation of the balloon catheter the elasticity of the liner will cause the liner to naturally

retract to its original configuration having the sleeve, or liner, disposed on the balloon catheter. Were the sleeve or liner or Hammerslag to be expanded and deformed beyond its elastic limit, as suggested by the Examiner in the third paragraph of the third page of the instant Official Action, it is believed that the liner, just as the artery wall itself, would likely rupture and split. Furthermore, it would appear that it would be impossible to convey a tapered liner, which closely conforms to the interior wall of the artery, to the desired location as suggested by Hammerslag. If necessary, Applicant would submit an affidavit to this effect if the Examiner does not concur with Applicant's submission.

With the foregoing points in mind, Applicant submits that independent Claims 1, 35, and 37, as originally presented, and independent Claims 13 and 24, as amended, are allowable over the references of record for the following reasons. A key feature of Applicant's invention is that the prosthesis or graft is not only expanded into the desired second diameter, but that the prosthesis or graft is "deformed" to achieve that configuration. As set forth in the specification on page 15, ll. 26-35, "[b]y use of the term 'deformed' is meant the material from which the graft, or prosthesis, 70 is manufactured is subjected to a force which is greater than the elastic limit of the material utilized to make tubular member 71." It is this feature that is not taught, suggested, or disclosed by any of the references or record.

As previously described, it is not understood how the liner, or sleeve or Hammerslag could be "deformed" in the

manner in which Applicant's prosthesis or graft is deformed, without apparently doing bodily harm to the patient, such as by rupturing his or her artery. The Wallsten graft is but another example of prior art grafts which can generally be classified as self-expanding springs, wherein the graft, after having been delivered to a stenotic site and released, is subjected to spring or spring-like forces associated with the construction of such grafts to cause the graft to enlarge and open outwardly within the body passageway. As previously pointed out, the Wallsten specification, on page 4, explains that it is preferable that the Wallsten prosthesis automatically enters into a radially expandable unloaded position "by itself". There is no deformation of the thread elements which comprise the Wallsten prosthesis. Likewise, the dilator of Didcott is not deformed, or subjected to a force greater than the elastic limit of the lattice structure of Didcott.

In claim 1, at line 16, it is specifically stated that the prosthesis is expanded and deformed at the desired location. Claims 13 and 24 have now been amended to recite that the tubular member of the prosthesis or graft has a "second, expanded and deformed diameter". Likewise the apparatus of claims 35 and 37 recite that the thin-walled tubular prosthesis is "expandable and deformable". Accordingly, Applicant respectfully submits that the independent claims of the present application, either as initially presented or as amended, positively recite a claim limitation which is neither taught, suggested, nor disclosed by any of the references of record. Accordingly, Applicant

respectfully requests that all the claims of the present application be allowed.

With respect to the rejections of certain claims under 35 U.S.C. § 112, Applicant would submit that claims 4-6 and 9-12 do contain additional method limitations; however, insofar as Applicant submits that the independent claims upon which these claims depend are allowable, the rejection under 35 U.S.C. § 112 is moot.

With respect to the rejection of claims 16 and 31, Applicant submits that such rejection should be withdrawn, on the grounds that those claims are not vague and indefinite when construed in light of the specification. Specifically, page 16, ll. 22-26 and page 19, ll. 8-15, explain that since the prosthesis or graft is not a "spring-like" or "self-expanding member", the prosthesis is not consistently applying an outward, radial force against the interior surface of the body passageway, in excess of that required to resist radial collapse of the body passageway." It is submitted that reading claims 16 and 31 in light of the specification, in particular those two passages, claims 16 and 31 are not vague and indefinite. Accordingly, withdrawal of the rejection of those claims under 35 U.S.C. § 112 is respectfully requested.

A number of claims have been added, which claims are directed to the use of tantalum in the claimed invention, and these claims find support in the specification at page 12, line 35.

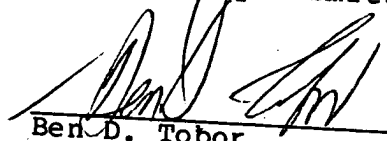
Applicant's attorney wants to take this opportunity to express his appreciation to Examiner Kartchner for the courtesies extended during the interview between Applicant's

attorney and Examiner Kartchner on May 8, 1987. No agreements were reached during the interview.

Applicant would like to direct the Examiner's attention to the "Second Supplemental Statement Under Rule 1.97" which was submitted in co-pending Application Serial No. 06/796009. If necessary, or if this reference to that statement in the related application is insufficient for the Examiner's purposes, Applicant will submit another Second Supplemental Statement Under Rule 1.97 for this case; however, the Statement will be identical to that of the related application.

Accordingly, allowance of all the claims of this application and subsequent issuance of Letters Patent are therefore earnestly solicited.

Respectfully submitted,



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